
**Urgent Medical Device Recall
L25 Bracket (Sold as part of CIVCO brand Biopsy Starter Kits and Biopsy Bracket)**

October 30, 2018

Attention: Ultrasound Department

This is to inform you of a product recall involving the Sonosite L25 Needle Guide Bracket which was sold within the product reference numbers identified below:

DEMOGPGUIDE	P03122-04	P06013-06	P12920-02	674-037
M001457100	P03122-05	P06013-07	P12922-01	674-038
P03122-01	P03122-06	P06013-08	P12922-02	674-039
P03122-02	P03122-07	P06013-10	P12924-01	674-057
P03122-03	P03122-08	P12920-01	P12924-02	674-057-10

Lot numbers: All Lot Numbers between A000012 – A050663, M000880 – M995980, and P022503

Manufacture Date Products with manufacture date between 03/2003 to 09/2018

Dear Valued Customer,

CIVCO has recently discovered an interaction issue with the L25 bracket and needle guide. You are being notified, as your facility has been identified as having received an L25 bracket from the affected manufacturing lots. The affected brackets were manufactured and included in the kits identified and manufactured between 03/2003 through 09/2018.

Description of the Problem:

During the attachment of the needle guide to the bracket over a cover, the interaction of the needle guide and bracket snapping together can cause a puncture or tear in the cover. Breaching the cover provides the risk of cross contamination of the reusable ultrasound transducer as well as the patient. This could lead to serious injury as it is not know what contamination could be carried forward.

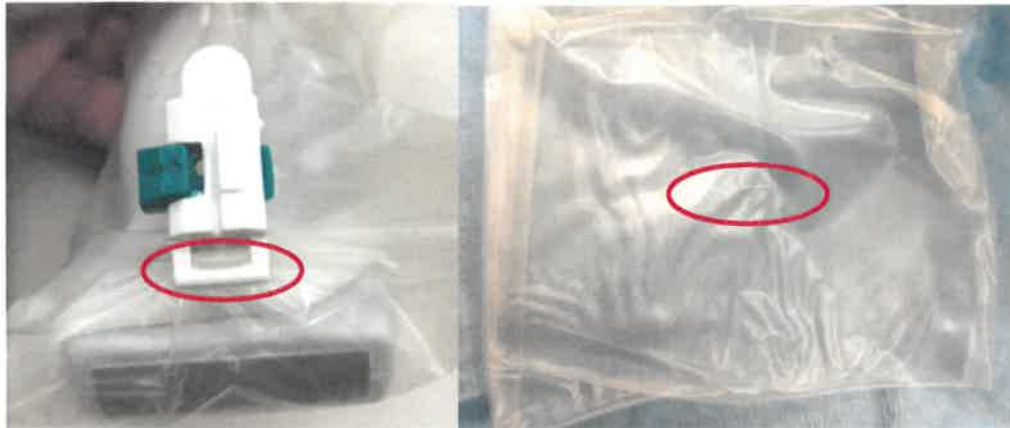


Fig 1. Assembled

Fig 2. Cover after guide attachment

Action to be Taken by the Customer:

CIVCO requests return of all L25 brackets which you may have. The reusable bracket may still be in your inventory. You can reference the manufacturing date located on the product label and return any manufactured between 2003.03 and 2018.09 for replacement. (see example below for manufacture date location)

REF 674-057

LOT XXXXXX



QTY 1

Needle Guide Bracket

Reusable non-sterile bracket for use with SonoSite® L25 series transducers

RU ONLY

[DA] Kønsetil nleesty	[IT] Supporto per guida ago	[RU] Держатель проводника иголы
[NL] Nasidgeloedbeugel	[JA] 注射器ガイドブラケット	[ZH-CN] 针器引导托架
[FI] Neulerohjälmen kannatin	[KO] 니들 가이드 브래킷	[ES] Soporte de guía de aguja
[FR] Bracelet du guide d'aiguille	[NO] Nålføringsbrakett	[SV] Fäste för nålguide
[DE] Nadelführungsklemme	[PT-BR] Suporte de guia de agulha	[ZH-TW] 針器托架
[EL] Πλάσιον Οδηγού Βελόνας	[PT-PT] Suporte do Guia de Agulha	[TR] İğne Kılavuzu Destegi



Date of Manufacture in YYYY.MM.DD format



Date of Manufacture: XXXX.XX.XX



CIVCO
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Kalona, IA 52247 USA
319.248.6757
WWW.CIVCO.COM



(01)00841438107174
(10)XXXXXX
(11)XXXXXX

674-057-B REV. B
H3806740570

If you no longer have the product labeling, please treat the bracket as one which needs to be returned.

To return the bracket and schedule replacement contact your Account Representative by phone at 800-445-6741 or 319-248-6757 or via email at order@civco.com.

A response form is enclosed for your completion by November 16. Please return the form even if you do not have any kits or brackets remaining in your inventory.

Transmission of this Recall Notification:

This notice is being communicated to all customers who have purchased a kit in which a bracket is contained from affected lots. CIVCO requests you provide this notification to the appropriate personnel within your facility. If the affected product was distributed outside of your organization, please notify those locations down to the medical facility level.

Thank you for your cooperation and communication on this issue. Please feel free to contact me if you have any questions or concerns regarding the above information.

Sincerely,

James Leong
Regulatory Manager
CIVCO Medical Solutions

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Return By: 16 November 2018

I have been informed of the recall notice by CIVCO Medical Solutions involving the L25 Bracket.
This notice has been read and understood by the responsible party involved.

1. _____ I have reviewed my inventory for the affected products and no longer have any in stock.

2. _____ I have reviewed my inventory for the affected products and I need a Return Authorization Number to return the product.

Quantity Lot # if Known

3. _____ Other, please provide details.

Facility Name

Street Address

City, State

Phone

Print Name / Title

Signature

Date

Please return this certification by FAX at 319-248-6660 or email to order@civco.com.
Attn: L25 Bracket at 319-248-6660, even if you no longer have any kits or brackets remaining in your inventory.

Please contact a CIVCO Customer Service representative for additional assistance. You may reach your Customer Consultant by calling CIVCO Medical Solutions, Multi-Modality Imaging, at 800-445-6741 or 319-248-6757 between 7:00AM and 5:30PM CST. You may also contact us via email at order@civco.com.

Thank You.